UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A.,	:	
Plaintiff,	:	15-CV-08725 (GBD)
v.	:	June 19, 2018
SANOFI,	:	500 Pearl Street New York, New York
Defendant.	:	

TRANSCRIPT OF CIVIL CAUSE FOR TELEPHONE CONFERENCE
BEFORE THE HONORABLE ROBERT W. LEHBURGER
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

For the Plaintiff: NONE STATED ON RECORD

For the Defendant: JOHN A. NEUWIRTH, ESQ.
Weil, Gotshal & Manges, LLP
767 Fifth Avenue, 25th Floor
New York, New York 10153

Court Transcriber: SHARI RIEMER, CET-805
TypeWrite Word Processing Service
211 N. Milton Road
Saratoga Springs, New York 12866

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THE PLAINTIFF: . . . . Sanofi-Genzyme used diligent efforts to achieve something known as the approval milestone, that is the approval of Lemtrada by a date certain for the treatment of multiple sclerosis.

The second issue in the case, at least as it relates to Lemtrada, relates to whether or not certain sales milestones of 400 million were met within a defined sales measuring period. At issue in this motion are documents recently discovered, recently created, and recently confirmed to exist. The last date of confirmation occurred in a deposition of May 2018 with a individual who had direct substantive knowledge. Our understanding and the existence of these documents were not known to us until after Your Honor's order of November in which you ruled that certain documents post July 2016 were relevant to the matters to be litigated in the case because they gave insight as to things which could have or should have been done during the relevant period in the litigation.

Here, there is what we would characterize as a specific and relatively narrow category of documents. They relate to a decision recently to initiate a trial, a Phase 3 trial, which is an approval trial in something known as primary progressive multiple sclerosis. As the documents we submitted as part of our letter motion show unequivocally, this trial or trials of this nature were considered in 2011

all the way through 2015 but were rejected for budgetary reasons. We've also included evidence that, at least with respect to an analogous antibody known as GLD52, it was the considered view of Sanofi and Genzyme that such activity would not only enhance the image of Lemtrada, but it would also potentially generate revenue in excess of $2.3 billion a year.

In addition, we recently learned at a deposition in May 2018 that in 2012 relevant executives were informed that a PPMS study would meet the definition of unmet need and would satisfy what's known as the requirements for fast track and priority review. We just literally this Thursday got testimony from Marc Esteva, the CFO of Genzyme, that in his view the loss of fast track and priority review cost Genzyme eight months of review. Therefore, the question of why a PPMS study, as was recommended in 2011 and through 2015, was not conducted in our view is highly relevant.

THE COURT: Okay. But that's what --

THE PLAINTIFF: It's not --

THE COURT: Let me -- let me stop you there. That -- but that's what my concern -- and you already know the reason it wasn't done or at least that it was professed, I should say, the alleged reason, i.e. budgetary reasons. But you already have documents, I assume, from a prior -- but tell me if I'm wrong, from a prior period, 2011 to I guess 2015, that addressed the question of why they did not pursue

Lemtrada in PPMS at that time. I understand that documents reflecting their current initiative may reflect reasons why they are choosing to do it but that doesn't really -- now, but that doesn't really answer the question of why they didn't before. Do -- does it? That's what I'm trying to weigh in the calculus here.

THE PLAINTIFF: Absolutely, Your Honor. And if Your Honor will look at the exhibit to Sanofi's response, and it lays out the category of documents that we're seeking, and I can explain in detail what each one of these categories are particularly relevant and, hence, in the proportionality test, as set out by Magistrate Pitman, should be produced. What happened --

THE COURT: I -- wait, wait, wait. I don't have time to go through each category --

THE PLAINTIFF: Okay.

THE COURT: -- by detail. I just want to understand why is a decision to go forward made in 2017 relevant to a decision in 2011 not to go forward?

THE PLAINTIFF: The specific rationales for why they decided today to spend the money to move forward on PPMS are directly relevant because they show that PPMS, in their view, has a high probability of success, that the decision to do this study with Lemtrada as opposed to another anti-CD52 antibody was driven by desire, which was critical to our

theory of the case, to avoid paying the milestone.

In addition, the documents requested show the communications with the FDA and set forth the parameters of what that clinical trial would look like and are important to our experts to be able to establish that that PPMS study would have been a study that was acceptable to the FDA. In addition, we had asked for the context of those decisions, particularly if any consideration was made that the reason to delay the launch, which would occur now and would be developed in documents now was driven by motivations such as the termination or end of the CVR agreement. I am --

THE COURT: Wait, so again, so that still, in my mind, doesn't directly get to the relevancy to the decision at an earlier point in time. I understand that at one of our previous hearings I did agree that certain documents after the fact are relevant because they may reflect decisions made previously, but there I was talking about just one year later or one-and-a-half years later. Whereas this was talking about something allegedly relevant to a decision made six years ago. And the question of whether something is feasible in 2017 versus 2011, that, you know, is a factor, among others that will make this potentially a very collateralized issue of limited relevancy.

But let me -- let me just switch to the defendant on this for a minute because I have -- I have some questions --

I'm sorry, but yeah, let me switch to UMB on this -- I'm sorry, Sanofi, I'm going back and forth on the issues -- of why they don't want to do this and why it's so burdensome.

MR. NEUWIRTH: Sure, Your Honor, thank you. It's John Neuwirth. A couple of preliminaries which the Court is aware of and I'll be very brief. First of all, the Court knows full well how extensive, how expensive, and how burdensome discovery in this matter has already been. Document production has already been completed, and that was a Herculean undertaking which was accomplished. There's a July 29th, 2016, cut off or documents in this case. Obviously, the documents that UMB is seeking now extend beyond that agreed-upon cutoff.

THE COURT: Right, but isn't this information they learned about recently?

MR. NEUWIRTH: It is. It is, Your Honor, and there are a lot of things that potentially could be happening now. And as Your Honor has correctly pointed out, we are divorced by six, seven years from 2011, and the answer can't be that plaintiff, especially considering what they already know -- and I think that's extremely important, they know the fact that there's a study with respect to PPMS. Now what else do they need to know? They know that. They can make that point if they want to. It can't be that they can delve into, at this point in the case, everything that is currently going on.

That is burdensome. Obviously, an additional document production, from our perspective after everything that we have already done, is a burdensome, costly exercise and certainly not proportional, as Rule 26 requires, to the needs of the case.

THE COURT: Okay. So let me -- let me ask you this. What -- you have agreed to produce the items set forth in a letter to me of June 7th; is that correct?

MR. NEUWIRTH: We have.

THE COURT: Okay. So -- and then there are the set of categories of documents that UMB seeks that are set forth, as I have it, in an email dated May 22nd. And there never bullets, and I want to ask you about three of them. So starting from the bottom, there's the most recent -- on the second bullet from the bottom, the most recent draft or final version. That's a single document. Why can't -- can that be -- do you have that and can that be reduced relatively easily?

MR. NEUWIRTH: Your Honor --

THE COURT: And why shouldn't it be, if you think it shouldn't be?

MR. NEUWIRTH: Your Honor, we have the brand plan as well as the strategic plan, and we could produce that with relatively minimal burden. The issue is it has a lot of other information in it that is wholly unrelated to PPMS with respect to forecasting and budgeting which we think would be

inappropriate given what plaintiff is seeking. So if what the Court is saying is can you produce that document, the answer is yes. But we would want to redact a lot of information that we think has nothing to do with this issue.

THE PLAINTIFF: [Inaudible]

THE COURT: Wait, hold on. And let me -- let me ask you about the one above it, the integrated development plan. What about that?

MR. NEUWIRTH: We understand, Your Honor, that that does not exist for Lemtrada currently.

THE COURT: Okay. Okay. And lastly, the bullet that's the forth from the top, documents sufficient to show the internal deliberative process resulting in the decision to abandon development of GLD52 in favor of Lemtrada. I -- you know, one could imagine documents that address the issue of whether to proceed and there being discussion in contrast to previous years and perhaps addressing why is it being now when it wasn't done previously. I'm not saying there is. Obviously, I don't know. But I could see that as a possibility. Why can't you or could -- what would be involved in getting documents sufficient to show the internal deliberation? And I -- this has deliberative process. But really what I -- well, that is the deliberative process in the decision to abandon development.

MR. NEUWIRTH: Your Honor, we think that the

documents that we've offered to produce will shed light on that issue. We think anything beyond that which necessarily will require a search of correspondence and emails is the same type of burdensome process that we have now completed in the case and will require a reopening and a real burden to us. So we think that the documents -- and we have them and we could produce those relatively promptly. We think that the documents that we've already identified and offered to produce will shed light on that issue.

We think going beyond that into more deliberative information which is -- which could perhaps, I don't even know, perhaps could reside in emails and other types of informal communications like that is an expedition which certainly is going to be burdensome, time-consuming, and I know we're going to get to the schedule next, and costly. And completely out of proportion to where we are right now.

THE COURT: I'm not going to order any electronic search on this. I am just trying to figure out if there are documents beyond what's in the bulleted list that make sense and is proportional. In the various committee documents that you are producing, I see reference to final minutes and meeting minutes, are those all committees that would have been assessing whether or not to proceed with this -- with Lemtrada in PPMS?

MR. NEUWIRTH: Yes.

THE COURT: Okay. So -- okay. Well, that's helpful to know. All right.

is there anything else plaintiff wishes to say on this issue? I'm sorry.

THE PLAINTIFF: Yeah, I would only say two things, Your Honor. One, we do think that this -- and again, this is not burdensome because they maintained these in a separate database. The material communications with the FDA about the clinical design of the trial are relevant. In the alternative, we would ask that there be some way in which we have an understanding of whether or not there's any distinction between the clinical trial as proposed to the FDA today and the clinical trials as proposed by internal clinical development people at Genzyme as late as 2015.

The second thing I would point out is there is a protective order in this case, and the redactions, other than the redaction as was previously agreed for forecasts past 2019, is not necessary as there is a protective order because it's not just the PPMS study itself but the PPMS study in context.

And the last point I would make, Your Honor, is I do think there should be some effort, maybe not electronic discovery, but I do think the plaintiff is absolutely entitled to know whether or not the decision to move from GLD52 to Lemtrada was in any way influenced by the Bayer royalties, the

probability of not having to pay the CVR payments because that's absolutely 100 percent the core and relevant in claims being made by the plaintiffs in the count and in this case. If, as we know when we send these documents to the court if necessary, a decision was made to delay all of these PPMS studies past 2020 when the CVR agreement terminates -- I'm not asking for an electronic search, but some good faith effort to make a determination as to whether there has been a chart termination outside of the final versions of these documents had any consideration of things which under the CVR agreement under the definition of diligent efforts, they are prohibited from considering.

THE COURT: Right, so -- and -- but as I understand it, again the relative time period is somewhere in I think it was 2016 or so up until then, maybe '17. But the --

THE PLAINTIFF: '16.

THE COURT: '16. Okay. But again, documents going precisely to the issue, which I agree is a core issue, should have been produced in connection with whatever production has already occurred. But again, these are documents that are going to a decision made later about whether to drop another drug and pursue Lemtrada. And at this point, it's just -- it's just going to be too burdensome in my view and not proportional given the relevancy of this category of documents to do anything more fulsome than the following, which is I am

going to order that Sanofi produce all of the materials it listed in its letter of June 7. They also shall produce the brand plan and strategic plan, both 2017 and 2018 if there is one, and you can redact but only as to other products. Why would you need to redact anything beyond that?

MR. NEUWIRTH: Your Honor, thank you for asking. There are, as we understand it, projections and financial forecasts in those documents which go out into the future and relate to, among other things, product sales, milestones, 244 [Ph.], which as the Court knows, are claims which are not in this case. That's the law of the case. And so it's not that were worried necessarily, and obviously it's irrelevant, and we will redact materials respect other products. There's that issue, but there's also the issue about what this plaintiff is entitled to see given where we are in this case. And with respect to some of the forecasts and budgeting with respect to issues that the Court has ruled are not in this case, that is material that we want to redact as well.

THE COURT: Have you -- have you previously produced documents about forecasting of what sales were going to be like in the future? Doesn't that in some way address the damages here potentially?

MR. NEUWIRTH: We produced, Your Honor, pursuant to one of your orders in a -- in a previous hearing, documents such as that through last year. So that material has been

produced.

THE COURT: All right. And when you say through the last year, you mean as created through last year and -- but projecting out into the future beyond that, correct?

MR. NEUWIRTH: Yeah.

THE PLAINTIFF: Yes, Your Honor, pursuant to prior discussions, we had -- the projections were truncated as of 2019. And just on the projection point, Your Honor, that's precisely the point of these documents is that to the extent they show productions into the future, those projections include parts of the sales that would be garnered both as a halo effect on the relapsing-remitting MS and as well as PPMS sales themselves.

So by allowing rejection of forecast and sales projections and discussions of how PPMS can help you sell an RRMS drug and how it encourages people to have a greater belief in your product even if you don't do the trial ultimately, that neuters the very purpose for why these documents are so significant because, as Your Honor rightly pointed out, that which is today to the extent it's relevant and it is, can be projected backwards during the relative time period.

And I would make one point which is that the endpoint of July 2016, obviously, is a discovery cut off. But the initiation of a PPMS study even as early as 2016, simply

because it's what's known as a halo effect, could have, in our view, made the achievement of the $400 million milestone much more likely. And in fact, I will also point out to Your Honor that in December of 2016, the trustee actually sent a letter to Sanofi asking them to do this very study. So there is a -- there is a -- it's not 2011 that we're focused on per se. It is obviously relevant, but it is the entire arc from 2011 all the way through to July 2016 -- because their own internal documents, and we believe this is exactly what the strategic plan documents will show, just initiating the trial itself showing commitment to the MS patients, which is what the Terry Murdock document we attached to the motion says, creates value for the product that can increase sales regardless of whether the PPMS study comes out positive or not.

THE COURT: All right. You -- okay. All right.

MR. NEUWIRTH: Your Honor, just to be clear, one last word on that.

THE COURT: Yeah.

MR. NEUWIRTH: Yes, just to be clear, in your prior ruling, we faced a similar issue as to how long these projections should go out, what are the plaintiffs entitled to see, and Your Honor ruled 2019. That's what we have previously produced to them. We think anything more is unnecessary. That's all.

THE COURT: Well, I send no reason to redact it,

though, which is different than whether you need to go find and collect other materials. So I think that they should be produced but it does not need to be redacted.

All right. Next item is the question of extending discovery, and I understand you have agreement on that. But you haven't given me any rationale as to why it's necessary, so someone explain that to me.

MR. NEUWIRTH: Your Honor, why don't I -- it's John Neuwirth -- why don't I start? We do have agreement on this issue except for one issue with respect to depositions which we can discuss. The rationale largely has to do with I think two things. One, obviously, the time to complete document production was significant. That's now complete, which is terrific. Depositions are already underway. There have been seven depositions to date.

But the main reason for the need for the extension is to accommodate the remaining depositions. The parties have already agreed on a couple of extensions of the limit on the number of depositions. The Federal Rules, obviously, as that Court knows, provide for 10 depositions of seven hours each for each party. We earlier agreed to extend that number -- to increase that number from 10 to 20. And then when plaintiff's amended the complaint to add the production of milestone claim, we agreed to increase that number from 20 to 25, still, obviously, with the seven-hour time limit.

Seven of those depositions, as I've said, have already taken place. We've provided dates for 16 others to the plaintiffs. Only three of those dates have been confirmed by the plaintiffs at this point. Perhaps that's because plaintiff wants to hear the Court's position with respect to its most recent proposal with respect to how many depositions should be permitted per side. But again, seven have taken place, 16 more we provided dates for, but they have not yet been scheduled --

THE COURT: Right. Okay.

THE PLAINTIFF: Other than three of them. But the main reason, Your Honor, that we need the extension is there's a lot of depositions that still need to take place. Many of them are overseas where we have already been and will be going back. Those take multiple days, obviously, to accomplish. That's the main reason, Your Honor.

THE COURT: Okay. And just remind me, to what extent -- how -- to what extent have there been extensions previous to this? I just -- I don't have that in mind -- of the discovery schedule?

MR. NEUWIRTH: This would be the fourth extension, Your Honor, of the schedule in the case. The case has obviously over time changed in both scope, [inaudible] with respect to the claims, but this would be -- this would be the fourth extension.

THE COURT: Okay. All right. And -- all right. So on the -- before we decide the extension because I know that could be affected by the number of depositions, although in some respects it shouldn't.

But nevertheless, let's discuss number of depositions. So as I understand it, Sanofi is taking the position there should be 25 depositions, meaning 25 persons or I guess one of those would also be a 30(b)(6). And secondly, UMB takes the position that it should be done by hours and that it would be 210 hours if I'm not mistaken. And that number of hours is greater than, certainly, the number of hours that would be and Sanofi's proposal, but what concerns me most about UMB's proposal is the following. It -- theoretically, you could take that and depose 60 or more people because you could do and a half-day deposition. Are you proposing the 210 hours for more no more than 25 people or are you -- is it for an unlimited number of persons?

THE PLAINTIFF: Your Honor, we would have no intention of taking 210 one-hour depositions or anything along those lines. What we had suggested initially to Mr. Neuwirth and his team was changing the -- changing the 25 230, but not counting bodies, because some of those 30 can be short depositions, and putting a per hour cap on the total fact discovery. So if you thought of it, we would -- we would want to 210 hours. We would anticipate no more than 30

depositions.

But the problem, Your Honor, arose at the beginning when in response to the mandatory Rule 26 disclosures, Sanofi identified hundreds of knowledgeable individuals, and then in response to the addition of the protection milestone, they identified 2,500 knowledgeable individuals on that one count alone. So they've given us 2,700 names, and we're trying to take a very reasonable number of depositions.

THE COURT: Well, the number of names is sort of -- I'm not sure what the right word is to describe it, but of course, depending how one -- liberal one wants to be in responding and providing people with knowledge, that can be either interpreted very broadly or very narrowly. And certainly, they -- Sanofi or both parties should be letting each side know what part -- what the parties played and you can discern that partly from the documents so you can work with each other in determining who should be deposed. But I don't think that Sanofi would have intended that 2,300 people be deposed.

THE PLAINTIFF: No, no, of course not. But it's just -- it just makes it difficult to figure out who the key ones are, you end up spending a little time that perhaps is unnecessary. We anticipate the depositions for a number of people will be shorter than seven hours, and it's entirely possible that a deposition of some individuals may be a little

longer than seven hours. And if we had a reasonable hour clock on the entire thing we think that it would be most appropriate.

MR. NEUWIRTH: Your Honor, you know, at some point in a case enough is enough. In the rules of proportionality, the amendments to the Federal Rules of Civil Procedure, have to mean something. We agreed consensually to move the deposition limit hear from 10 to 20 to 25. That is more than enough, Your Honor. There are very few cases, if any, that I'm aware of that have a deposition amount that reaches that level. Magistrate Judge Parker in the Almaty, Kazakhstan case which she decided in May, talked about 14 or 15 depositions as being extensive. We are already at 25.

Yes, of course, we identified a large number of individuals in response to initial disclosures but plaintiffs know full well who is relevant, and they've been taking those depositions. They just want more, just like they want more document discovery. Enough is enough, Your Honor. This is an entirely one-way discovery burden. We are taking to date right now one, maybe two, depositions of plaintiff. They already had 25 of us. Now they want to go up to at least 30.

And the burden attendant to having just an hours cap is significant, Your Honor. Is the deposition to be three hours? Is it going to be nine hours? What are we going to know? Where is that deposition going to be? Are we going to

have to go to Europe for four days to do a three-hour deposition? Twenty-five depositions with a definitive hours limit of seven hours, that rule -- that seven-hour rule is in the Federal Rules for reason, so parties can plan and not be unduly burdened. Anything beyond 25 depositions, Your Honor, which is a significant, significant number, is -- should not be permitted at this point. It's just not proportional.

THE COURT: Well, look, on you -- I typically am a fan of time limits for trial, and I have used it to -- when I was litigating to some extent for depositions but never for the full set. But I have to say when I saw these numbers of 25 and then what equates to 30, I said to myself, you know, I understand this is a sizable case. I understand what drug development cases are about. But why am I seeing more than 20 per side? So I thought 20 would be sort of the outside number.

And what I'm going to say is it's going to be 25 limited, as they're supposed to be, to whatever hours they are pursuant to the rules, seven hours. However, A, if UMB thinks there is good reason why a person should be deposed for more than seven hours, such as if they are a key player and there's a lot to ask them about, they can -- I -- they should ask you if they can go longer. But if another day is done with them then that means one less witness. But if it's a half-day, you know, that's the type of thing where you could cooperate and

say, okay, well, let's just take the rest of your half-day with somebody ask. But 25 seems an appropriate limit.

I also assume you're going to have 30(b)(6) depositions, and given the wide ranging information, I wouldn't be surprised if, certainly for Sanofi, more than one person were required to answer the various categories. And on the one hand that -- so that 30(b)(6) deposition is one deposition. However, to the extent people who are testifying and designated for the 30(b)(6), if they are being deposed in their individual capacity in addition to 30(b)(6) testimony, then that counts as an additional deposition per person. If it's solely 30(b)(6) and not individual capacity then it's just part of their 30(b)(6).

All right. And look, again, also if for any reason UMB feels they in good faith haven't been able to get what they need and you guys can't work it out, UMB will come to me and say, look, we need another deposition or two, 25 was enough for X reasons, and if there's good reason then I'll consider that. So that's what we're going to do.

And then in terms of the extension, I'll grant a three-month extension, but I do not want to see more extensions. So no more extensions absent compelling circumstances.

Anything else? Plaintiff?

THE PLAINTIFF: Not from the plaintiff, Your Honor.

Thank you very much for your time this morning.

THE COURT: Sure. Defendant?

MR. NEUWIRTH: Not from Sanofi, Your Honor.

THE PLAINTIFF: Thank you, as well.

THE COURT: All right. Thank you all, and good luck with the depositions.

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I certify that the foregoing is a court transcript from an electronic sound recording of the proceedings in the above-entitled matter.

Shari Riemer, CET-805

Dated: June 19, 2018